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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,135	06/25/2001	Y. Tom Tang	PF-0585 USN	5219

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EXAMINER
MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,135	TANG ET AL.	
	Examiner	Art Unit	
	Prema M Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-40* is/are pending in the application.

4a) Of the above claim(s) *30,32-34 and 37-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21,23,26-28,31 and 35* is/are rejected.

7)☒ Claim(s) *22,24,25,29 and 36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-20 have been canceled previously. Claims 22-29, 35-36, amended claims 21, 31, (2/17/2004) are under consideration by the Examiner. Claims 30, 32-34, 37-40 have been withdrawn from consideration.

2. Receipt of applicant's arguments and amendments filed on 2/17/2004 is acknowledged.

3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 2/17/2004:

(i) the objection to the specification for absence of an abstract.

4. Applicant's arguments filed on 2/17/2004 have been fully considered but were non-persuasive. The issues remaining and new issues are stated below.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

6. Applicants again request examination of the subject matter of the non-elected process claims 32-34 and claims 39-40 (see In re Ochiai (37 USPQ2d 1127 (Fed. Cir. 1995)), in which a new, unobvious material is used in a known process. Ochiai determined that a process was free of the prior art if it employed a product, which was free of the prior art. However, only if the product claims of examined Groups I-II (drawn to polypeptides and polynucleotides) are found allowable, the subject matter of the claimed product will be rejoined with the process claims, if the process claims are of the same scope as the allowable product claims (insofar as the new claims do not precipitate

new rejections). Therefore, claims drawn to a method of using the polypeptide and polynucleotide will be rejoined with these products are found allowable.

Claims 30, 32-34, 37-40 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112, first paragraph

7. Claims 21, 23, 26-28, 35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained for reasons of record set forth at pages 3-5 of the previous Office action of 10/15/2003.

Applicant argues that the limitation encompassing polypeptide variants of claim 21 have been canceled and that claim 21 has been amended to recite that the claimed biologically active fragments have FHL3 activity. Applicants also argue that claim 31 has been amended to recite that the claimed polynucleotide variants encode a polypeptide having FHL3 activity. However, contrary to Applicant's arguments, the specification and claims do not indicate what are the distinguishing attributes of a biological fragment or variant having FHL3 activity because there is no written description of such activity in the instant specification.

Applicant argues that given SEQ ID NO:2, one of ordinary skill in the art would recognize a polynucleotide at least 90% identical to the polynucleotide sequence of SEQ ID NO:2, said polynucleotide encoding a polypeptide having FHL3 activity. However, contrary to Applicant's arguments, here there is no recitation of specific functional

features with a definition of structural features, which is a common basis by which courts have found invalid claims to DNA. Therefore, as in *Lilly* and *Fiers*, due to the reliance on functional characteristics of the polynucleotides and polypeptides recited in the claims, for which functional characteristic there is no adequate written description, the present inventors were not in possession of the claimed polynucleotide variants at the time of filing the instant invention.

8. Claims 21, 23, 26-28, 31 and 35 are rejected under 35 U.S.C. 112, first paragraph for lack of enablement.

This rejection is maintained for reasons of record set forth at pages 5-6 of the previous Office action of 10/15/2003.

With respect to claim 31, Applicants argue that the disclosure amply enables the claimed invention and given the sequence of SEQ ID NO:2, one of ordinary skill in the art could readily identify a polynucleotide comprising a naturally occurring polynucleotide sequence at least 90% identical to a polynucleotide sequence of SEQ ID NO:2, using well known methods of sequence analysis without any undue experimentation. However, contrary to Applicant's arguments, Applicant's claims encompass polynucleotide sequences that encode polypeptides that have "FHL3 activity".

The claimed genus of polynucleotides encompasses variants that share activity, however, the specification does not teach how to make a polynucleotide sequence encoding a polypeptide having an amino acid sequence less than SEQ ID NO:1, that would share "FHL3 activity". Applicants are not claiming polynucleotide sequences that are "probes" but polynucleotide sequences that encode proteins. The specification only enables polynucleotides encoding proteins of amino acid sequences set forth in SEQ ID

NO:1 and is not enabled for a polynucleotide encoding a polypeptide having an amino acid sequence anything less than what is disclosed in SEQ ID NO:1, the claimed polypeptides having specific characteristics.

The issue in the instant case is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. The recitation of "FHL3 activity", is not a sufficient functional limitation.

Furthermore, the instant specification does not provide the guidance needed to use these polynucleotides as claimed. Even though Applicants have recited a functional limitation for the polypeptide in the instant claims, Applicants have not taught how to make the instant polynucleotides encoding polypeptides with "FHL3 activity" as recited in claim 31. The instant specification does not teach which polynucleotides encoding polypeptides would predictably be associated with that function. There is no guidance in the specification for how to make and use polynucleotides encoding proteins having the amino acid sequences anything less than that disclosed in SEQ ID NO:1.

Applicants arguments on page 16 that the standard is that routine experimentation is required to identify the numerous embodiments is a position that has been routinely dismissed by the courts, as shown by the CAFC decision in Genentech, Inc. v. Novo. Nordisk, 42 USPQ2d, 100 (CAFC 1997), in which the decisions in In re Fisher, Amgen Inc. V. Chugai Pharmaceuticals Co. Ltd., and In re Wands were considered as the controlling precedents in determining enablement issues where protein and recombinant DNA issues are concerned. These decisions have been relied upon in the instant rejection and by the Court because they show that the judicial interpretation of the first paragraph

of 35 U.S.C. § 112 requires that the breadth of claims must be based upon the predictability of the claimed subject matter and not on some standard of trial and error. To argue that one can make material embodiments of the invention and then test for those that work in the manner disclosed or that the instant claims only encompass the working embodiments is judicially unsound. Unless one has a reasonable expectation that any one material embodiment of the claimed invention would be more likely than not to function in the manner disclosed or the instant specification provides sufficient guidance to permit one to identify those embodiments which are more likely to work than not, without actually making and testing them, then the instant application does not support the breadth of the claims.

Further, In re Wands determined that the repetition of work which was disclosed in a patent application as producing a composition containing an antibody, which is a naturally-occurring compound, did not constitute undue experimentation even if the antibody produced thereby was not identical to those that were disclosed in that application. To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of the work that is described in the instant application but a substantial inventive contribution on the part of a practitioner which would involve the determination of those amino acid residues of the disclosed naturally-occurring protein, which are required for functional and structural integrity of the protein. It is this additional characterization of the disclosed protein that is required in order to obtain the structural data needed to permit one to produce the claimed polynucleotide encoding a protein, which meets the structural requirements of the instant claims that constitutes undue experimentation.

Furthermore, Applicants argue that claim 21 has been amended to recite that the claimed immunogenic fragments consist of at least 5 contiguous amino acid residues of the amino acid sequence of SEQ ID NO:1. Applicants are reminded that it is well known in the art that at least a stretch of 6 amino acids is required for eliciting an antibody response. (Harlow et al. 1988). Harlow also discloses that generally, peptides of approximately 10 residues should be used as a lower limit for coupling. The specification (page 5, lines 18-21) merely outlines that immunogenic fragments of 5-15 amino acid residues can be used to elicit antibodies. This is not adequate guidance as to the nature of the immunogenic fragments that may be constructed, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. Therefore Applicants have not presented enablement commensurate in scope with the claims.

Claims 21, 23, 26-28, 35 are rejected under 35 U.S.C. 112, first paragraph insofar as they depend on claim 21 for its limitations.

Claim rejections-35 U.S.C. 112, first paragraph-new matter rejection

9. Claims 21, 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 21 and 31, line 4, recite "... having FHL3 activity" which language is new matter in the claim, since the instant specification fails to disclose this limitation. The specification fails to provide proper support for this language in the claims for the following reason:

The specification, page 12, lines 14-23, discloses that the invention is based on the discovery of a new human LIM domain protein homolog (LDPH), the polynucleotides encoding LDPH, and the use of these compositions for the diagnosis, treatment, or prevention of cancer and reproductive disorders. Furthermore, on page 43, lines 6-10, Applicants disclose that the activity of a sample containing LDPH is assayed by determining it's ability to promote differentiation in C2-AS cells. The specification does not disclose the specific "FHL3" biological activity as recited in the claims. The activity as disclosed in the specification is not equivalent to the specific biological activity recited in claims 21 and 31. This rejection can only be obviated by reciting the specific biological activity for which there is support in the instant specification.

Claim rejections-35 U.S.C. 112, second paragraph

10. Claims 21, 23, 26-28, 31, 35 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21 and 31 have been amended to recite "FHL3 activity". However, the claims are vague and indefinite because it is unclear what this activity is referring to. Is it a proliferation activity or a differentiation activity or some other activity? Furthermore, it is unclear what "FHL3" means. It is suggested that Applicants recite an activity for the protein, for which activity there is a basis in the instant specification.

Claim 31 remains indefinite in the recitation of the term "naturally occurring". Applicants argue that one of ordinary skill in the art would recognize that a "naturally occurring" sequence as recited in claim 31 is one that occurs in nature but Applicants also argue that the claim language does not preclude making such sequences synthetically.

Therefore, it is precisely for this reason (claims may encompass synthetic and naturally occurring embodiments) that the metes and bounds of the claim are unclear.

Claim 21 remains rejected for reciting "biologically active fragment". It is unclear what the metes and bounds of this limitation are because a single amino acid encompasses a "biologically active fragment" and meets the limitations of this claim since the meaning of the recitation "FHL3 activity" in the claim is unclear. Recitation of a specific biological activity of a fragment in the claim for which biological activity there is support in the instant specification, would obviate this rejection.

Claim 1, line 10, is improper because it recites "generates and antibody" rather than "generates an antibody".

Claims 23, 26-28, 35 are rejected as vague and indefinite insofar as they depend on the above rejected claims for their limitations.

Claim Rejections - 35 USC § 102

11. Claims 21 and 23, are rejected under 35 U.S.C. 102(b) as being anticipated by Morgan et al (1996).

This rejection is maintained for reasons of record set forth at pages 7-8 of the previous Office action (10/15/03).

Applicants argue that the reference does not read on claim 21, as currently amended, which now recites "a biologically active fragment of a polypeptide having the amino acid sequence of SEQ ID NO:1, said fragment having FHL3 activity". However, contrary to Applicants arguments, the essential disagreement appears to be the interpretation of what constitutes a "FHL3 activity" and since Applicants have not provided a definition for this specific activity in the instant specification, a biologically

active fragment of the polypeptide of the reference, would potentially be any amino acid and encompasses the claimed invention.

Claim Rejections - 35 USC § 103

12. Claims 26-28, 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morgan et al (1996).

This rejection is maintained for reasons of record set forth at pages 8-9 of the previous Office action (10/15/03).

Applicants argue that they have amended claim 21 to add a functional limitation for the claimed biologically active fragments. However, in the absence of a definition of "FHL3" biological activity in the instant specification or claims, it is unclear what "FHL3 activity" means. Therefore, the reference renders obvious the instant invention.

Conclusion

No claim is allowed.

Claims 22, 24, 25, 29, 36, are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (571) 271-0871.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
March 4, 2004